abbvie AbbVie NJ K133129
Traditional 510(k) Notification
510(k) Summary

510(k) Summary

Sponsor: AbbVie Inc.
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North Chicago, IL 60064

Contact: Katherine Wortley, Ph.D.
Director Regulatory Affairs
AbbVie Inc.
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Date Prepared: September 30, 2013

Device:

Trade Name: AbbVie™ NJ

Common Name: Naso-Jejunal Tube

Classification Name: Tubes, Gastrointestinal and Accessories
21 CFR 876.5980, Product Code KNT, Class II

Predicate Device: Entriflex™ Feeding Tube, K833621

Device Description:

The AbbVie™ NJ is a 10 FR, 152 cm, naso-jejunal (NJ) tube made of white radiopaque polyurethane. The distal coiled end region and bolus tip are coated with a water activated lubricant. The AbbVie NJ includes a silicone coated Stylet.

Device Intended Use:

The AbbVie NJ is intended to provide short-term enteral access for administration of medication to the small intestine.

Comparison of Product Characteristics:

The AbbVie NJ is substantially equivalent to the currently marketed predicate device, Entriflex Feeding Tube (K833621). Both devices are naso-enteric tubes. The tubes have the same fundamental structure and function. The predicate is a family of devices that vary in diameter (8, 10, and 12 FR) and length. The AbbVie NJ tube diameter (10 FR) falls within the range of the Entriflex product family. Duration of use (30 days or less), stylet feature, tube material (polyurethane), and anatomical delivery (through the nose into the small intestine) are the same as the predicate. Differences include tube length, distal end configuration, proximal end connector type, and sterility status. The indication for use for the AbbVie NJ (administration of medication) is within the indications for use of the Entriflex Feeding Tube (administration of feeding, fluid and medication).

Non-Clinical Performance Data:

The performance characteristics of the AbbVie NJ have been verified based on the conformance to applicable industry standards. The material composition of the AbbVie NJ shows acceptable performance across all biocompatibility protocols tested per ISO 10993-1:2009 *Biological evaluation of medical devices-Part 1: Evaluation and testing within a risk management process*. The AbbVie NJ was assessed for conformance to standard BS EN 1615:2000 *Enteral feeding catheters and enteral giving sets for single use and their connectors – Design and testing*. An assessment of the AbbVie NJ has been completed and shown to be acceptable per ISO 80369-1:2010 *Small-bore Connectors for Liquids and Gases in Healthcare Applications- Part 1: General requirements*.

Clinical Performance Data:

No clinical evaluations were performed or relied upon for the determination of substantial equivalence.

Conclusion:

The information provided within this pre-market notification demonstrates that the AbbVie NJ has no differences that would affect the safety or effectiveness of the device as compared to the predicate device, Entriflex Feeding Tube. The differences between the two devices do not raise new issues of safety or effectiveness. The AbbVie NJ is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 19, 2014

AbbVie, Inc.
Katherine Wortley, Ph.D., RAC
Director Regulatory Affairs
1 N. Waukegan Road
North Chicago, IL 60064

Re: K133129
Trade/Device Name: AbbVie™ NJ
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: May 15, 2014
Received: May 16, 2014

Dear Katherine Wortley,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -A

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K133129

Device Name: AbbVie™ NJ

Indications for Use:

The AbbVie NJ is intended to provide short-term enteral access for administration of medication to the small intestine.

Prescription Use _X____ AND/OR Over-The-Counter Use ____

(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -A
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